DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-470

Berlex Drug Development and Technology
Division of Berlex Laboratories, Inc.
Attention: John Hegarty, Regulatory Associate
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000

Dear Mr. Hegarty:

Please refer to your new drug application (NDA) dated March 20, 2002, received March 21, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FINACEA™ (azelaic acid) Gel, 15%.

We acknowledge receipt of your submission(s) dated April 18, May 14 and 30, June 6 and 14, July 30, August 30, October 8, 14 and 16, November 4, 8, 12 and 14 and December 6, 10, 16, 17, 19 (facsimile), 23 (2 facsimiles) and 24 (facsimile), 2002.

This new drug application provides for the use of FINACEA™ (azelaic acid) Gel, 15%, for topical application in the treatment of inflammatory papules and pustules of mild to moderate rosacea.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "FPL for approved NDA 21-470." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitments in your submission dated December 17, 2002. These commitments are listed below.

1. Description of Commitment: NON-CLINICAL TOXICOLOGY

   Conduct a study to determine the photoco-carcinogenic potential associated with azelaic acid 15% gel.

Protocol Submission:	Within 4 months of the date of this letter
Study Start:	Within 6 months of the date of the approval of the protocol
Final Report Submission:	Within 12 months after the study completion

2. Description of Commitment: NON-CLINICAL TOXICOLOGY

Conduct an alternative, dermal carcinogenicity study in transgenic mice (Tg.AC assay) with the azelaic acid 15% gel.

Protocol submission:	Within 5 months of the date of this letter.
Study Start:	Within 6 months of the date of the approval of the protocol
Final Report Submission:	Within 12 months after the study completion

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study finals reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Frank H. Cross, Jr., M.A., CDR, Senior Regulatory Project Management Officer, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

John Kelsey
12/24/02 11:28:03 AM
I am signing thhis letter for Dr. Wilkin in his absence.